

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2005 list were published in the Federal Register in January 2005.

### New Approvals

#### NADA Number: 141-241

Trade Name: Zimecterin-EZ™  
Ingredients: Ivermectin  
Sponsor: Merial Ltd.  
Approval Date: December 16, 2004  
Status: Over-the-counter  
Route: Oral  
Species: Horse  
Drug Form: Meal mixture  
Concentration: 36 milligrams per blister cup  
Indications: For treatment and control of the following parasites in horses:  
**Large strongyles** (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda*, and *T. serratus* and *Craterostomum acuticaudatum*  
**Small strongyles**: (adults, including those resistant to some benzimidazole class compounds) - *Coronocylus* spp. including: *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including: *C. catinatum*, *C. pateratum*, *Cylicocyclus* spp. including: *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including: *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Fourth-stage larvae  
**Pinworms** (adults and fourth-stage larvae) - *Oxyuris equi*  
**Ascarids** (adults and third- and fourth-stage larvae) - *Parascaris equorum*  
**Hairworms** (adults) - *Trichostrongylus axei*  
**Large-mouth Stomach Worms** (adults) - *Habronema muscae*;  
**Bots** (oral and gastric stages) - *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*  
**Lungworms** (adults and fourth-stage larvae) - *Dictyocaulus arnfieldi*  
**Intestinal Threadworms** (adults) - *Strongyloides westeri*  
**Summer sores** caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae  
**Dermatitis** caused by neck threadworm microfilariae, *Onchocerca* sp.  
Patent number: Pending  
Exclusivity: 3 years

21CFR 520.1194

#### ANADA Number: 200-343

Trade Name: Heifermax™ 500  
Pioneer product: 039-402  
Ingredients: Melengestrol acetate  
Sponsor: Ivy Laboratories, Div. of Ivy Animal Health, Inc.  
Approval Date: December 3, 2004  
Status: Over-the-counter  
Route: Oral  
Species: Cattle, heifer  
Drug Form: Liquid  
Concentration: 500 milligrams per pound  
Indications: For heifers fed in confinement for slaughter – for increased weight gain, improved feed efficiency, and suppression of estrus (heat).  
For heifers intended for breeding – for suppression of estrus (heat).  
Tolerance: 21CFR 556.380 Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound, melengestrol acetate, in fat of cattle.  
Withdrawal: Not required.

21CFR 558.342

## Actions Taken by FDA Center for Veterinary Medicine

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### ANADA Number: 200-377

Trade Name: Lincomed Soluble Powder  
Pioneer product: 111-636  
Ingredients: Lincomycin hydrochloride  
Sponsor: Cross Vetpharm Group Ltd.  
Approval Date: December 6, 2004  
Status: Over-the-counter  
Route: Oral  
Species: Swine, broiler chickens  
Drug Form: Powder  
Concentration: Each gram of soluble powder contains 0.4 gram of lincomycin  
Indications: Swine: For the treatment of swine dysentery (bloody scours).  
Broiler chickens: For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.  
Tolerance: 21CFR 556.360 Lincomycin: A tolerance for residues of lincomycin established for swine is 0.6 part per million in liver and 0.1 part per million in muscle. A tolerance for residues of lincomycin in chickens is not required.  
Withdrawal: Swine - zero days  
Chickens - zero days

21CFR 520.1263c

### ANADA Number: 200-386

Trade Name: Levamisole Hydrochloride Soluble Drench Powder  
Pioneer product: 112-051  
Ingredients: Levamisole hydrochloride  
Sponsor: Phoenix Scientific, Inc.  
Approval Date: December 17, 2004  
Status: Over-the-counter  
Route: Oral  
Species: Cattle, sheep  
Drug Form: Powder  
Concentration: 1.8 ounce pouch contains 46.8 grams of levamisole hydrochloride, 14.21 ounce bottle contains 362.7 grams of levamisole hydrochloride, and the 21.43 oz bottle contains 544.5 grams of levamisole hydrochloride  
Indications: Levamisole hydrochloride is a broad spectrum anthelmintic and is effective against the following adult nematode infections in cattle and sheep:  
Sheep:  
**Stomach Worms:** *Haemonchus contortus*, *Trichostrongylus axei*, *Teladorsagia circumcincta*.  
**Intestinal Worms:** *Trichostrongylus colubriformis*, *Cooperia curticei*, *Nematodirus spathiger*, *Bunostomum trigonocephalum*, *Oesophagostomum columbianum*, *Chabertia ovina*  
Lungworms: *Dictyocaulus filaria*  
Cattle:  
**Stomach Worms:** *Haemonchus placei*, *Ostertagia ostertagi*, *Trichostrongylus axei*  
**Intestinal Worms:** *Trichostrongylus longispicularis*, *Cooperia oncophora*, *Cooperia punctata*, *Nematodirus spathiger*, *Bunostomum phlebotomum*, *Oesophagostomum radiatum*  
**Lungworms:** *Dictyocaulus viviparus*  
Tolerance: 21CFR 556.350 Levamisole hydrochloride: A tolerance of 0.1 part per million is established for negligible residues of levamisole hydrochloride in the edible tissues of cattle and sheep.  
Withdrawal: Cattle - 48 hours  
Sheep - 72 hours

21CFR 520.1242a

## Actions Taken by FDA Center for Veterinary Medicine

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### Supplemental Approvals

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This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

**NADA Number: 141-147**

Approval date: December 16, 2004

This application provides for Type B and C labeling with a revised decoquinate range of 12.9 to 90.8 grams per ton and chlortetracycline range of 500 to 4000 grams per ton in the Type C complete feed, and decoquinate range of 90.9 to 535.7 grams per ton and chlortetracycline range of 4000 to 20,000 grams per ton in the Type C supplement feed.

*21CFR 558.195*

**NADA Number: 141-185**

Approval date: December 16, 2004

This application provides for Type B and C labeling with a revised decoquinate range of 12.9 to 90.8 grams per ton and chlortetracycline range of 500 to 4000 grams per ton in the Type C complete feed, and decoquinate range of 90.9 to 535.7 grams per ton and chlortetracycline range of 4000 to 20,000 grams per ton in the Type C supplement feed.

*21CFR 558.195*

### Suitability Petition Action

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Number:	04P-0551/CP1
Sponsor:	Intervet, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug omeprazole which differs from the pioneer product, UlcerGard™, Merial Ltd., NADA 141-227 by the following characteristics: The generic product will have a different dosage form (tablet) from the pioneer.
Action:	Approved January 28, 2005.

### Correction

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In the Suitability Petition Action section of last month's publication (January 15, 2005) the drug stated should have been omeprazole and not ivermectin in 04P-0551/CP1.

## **Actions Taken by FDA Center for Veterinary Medicine**

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### **Notice**

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The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the Federal Register of November 24, 2004 (69 FR 68384), to February 23, 2005. In the notice, FDA requested comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The agency is giving the extension in response to a request for additional time to allow interested persons to submit comments. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments> by February 23, 2005. For further information contact: Barry Hooberman, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-8557, e-mail: [bhooberm@cvm.fda.gov](mailto:bhooberm@cvm.fda.gov).